

## REMARKS

### *Restriction Requirement*

The Examiner has imposed a restriction between Group I (claims 1-20 and 33-39), Group II (claims 21-32), Group III (claims 40-45), Group IV (claims 46-49), and Group V (claim 51).

Applicants hereby elect Group I (claims 1-20 and 33-39), without traverse.

Applicants expressly reserve their right under 35 U.S.C. § 121 to file a divisional application or continuation application directed to the nonelected or other unclaimed subject matter during the pendency of this application, or an application claiming priority from this application.

Applicants request examination of the elected subject matter on the merits.

### *Status of the Claims*

Claims 1-64 are pending in this application. Claims 52-64 were previously withdrawn from consideration as drawn to nonelected subject matter. By virtue of this response to the current Restriction Requirement, claims 1-20 and 30-39 are elected for examination. By this amendment, claims 2, 13, and 34 have been canceled, claims 1, 3, 4, 9-12, 14, 15, 33, 35, 36, and 39 have been amended, and new claims 65-92 have been added. Accordingly, claims 1, 3-12, 14-20, 30-33, 36-39, and 65-92 are currently under consideration.

The amendments and new claims are supported by the specification. Claims 1, 12, and 33 were amended to incorporate the limitations of canceled claims 2, 13, and 34, respectively. Claims 3, 14, 35, and 36 were amended to remove dependence on canceled claims. Claims 4, 9, 14, and 15 were amended to clarify the claims by changing the term “polynucleotide” to the plural form “polynucleotides,” antecedent basis for which was provided in the claims as filed. The word “and” was added to claim 15 merely to correct a clerical error and to clarify the claim. The amendment to claim 9 to change dependence from claim 5 to claim 8 is supported, for example, on page 4, lines 1-11 and on page 46, lines 9-14. The amendments to claims 10 and 39

are supported, for example, on page 46, lines 9-14. The amendment to claim 11 is supported, for example, on page 26, lines 11-22. New claims 65, 73, 76, 83, and 90 are supported, for example, on page 35, lines 15-17. New claims 66-72 are supported, for example, on page 3, lines 9-16, on page 26, lines 11-20, and on page 46, lines 9-14. New claims 74 and 75 are supported, for example, on page 26, lines 11-20 and on page 44, lines 13-15. New claims 77-89 are supported, for example, on page 27, lines 3-16 and on page 44, lines 13-15. New claims 91 and 92 are supported, for example, on page 27, line 19 - page 28, line 3 and on page 44, lines 13-15.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned “**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**”

With respect to claim amendments and cancellations, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 252312007400. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: September 13, 2002

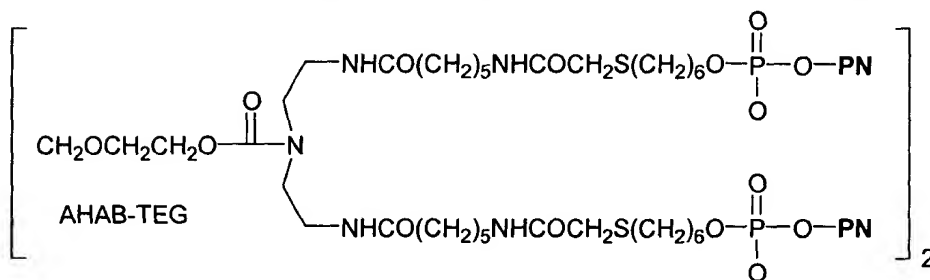
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

***In the Claims***

1. (Once Amended) A method of treating systemic lupus erythematosus (SLE) in an individual, comprising administering to the individual a conjugate comprising (a) a non-immunogenic valency platform molecule and (b) two or more molecules comprising double stranded DNA (dsDNA) epitopes which specifically bind to an antibody from the individual which specifically binds to double stranded DNA, wherein the dsDNA epitopes are polynucleotides, wherein affinity of the [dsDNA epitope] polynucleotides for the antibody from the individual is used as a basis for selecting the individual to receive or continue to receive the treatment.
3. (Once Amended) The method of claim [2] 1, wherein the polynucleotides are double stranded DNA.
4. (Twice Amended) A method of treating SLE in an individual, comprising administering to the individual a conjugate comprising (a) a non-immunogenic valency platform molecule and (b) two or more polynucleotides which specifically bind to an antibody from the individual which specifically binds to double stranded DNA, said polynucleotides consisting essentially of the sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1), wherein the apparent equilibrium dissociation constant ( $K_D'$ ) for the polynucleotides with respect to the antibody from the individual before or upon initiation of treatment is less than about 1.0 mg IgG per ml, and wherein said  $K_D'$  value or a functional equivalent thereof is used as a basis for selecting the individual to receive the treatment.
9. (Twice Amended) The method of claim [5] 8, wherein the polynucleotides consist[s] of the sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

10. (Once Amended) The method of claim [9] 12, wherein the platform molecule is



wherein PN is the polynucleotide.

11. (Once Amended) The method of claim 9, wherein the  $K_D'$  is less than about [0.5] 0.8.

12. (Once Amended) A method of treating SLE in an individual comprising:

(a) assessing affinity of an anti-double stranded DNA antibody from the individual with respect to a dsDNA epitope which is to be used in treatment, wherein the individual is selected for treatment based on said antibody affinity; and

(b) administering to said selected individual a conjugate comprising (a) a non-immunogenic valency platform molecule and (b) two or more of the dsDNA epitopes, wherein the dsDNA epitopes are polynucleotides which specifically bind to an antibody from the individual which specifically binds to double stranded DNA.

14. (Once Amended) The method of claim [13] 12, wherein the polynucleotides [is] are double stranded DNA.

15. (Twice Amended) A method of treating SLE in an individual, comprising

(a) assessing before initiation of treatment an apparent equilibrium dissociation constant ( $K_D'$ ) or a functional equivalent thereof for a polynucleotide in a conjugate

and an antibody from the individual which specifically binds to double stranded DNA, said conjugate comprising (a) a non-immunogenic valency platform molecule and (b) two or more polynucleotides which specifically bind to an antibody from the individual which specifically binds to double stranded DNA, said polynucleotides consisting essentially of the sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1), wherein the individual is selected to receive the treatment if the  $K_D'$  is less than about 1.0 mg IgG per ml; and

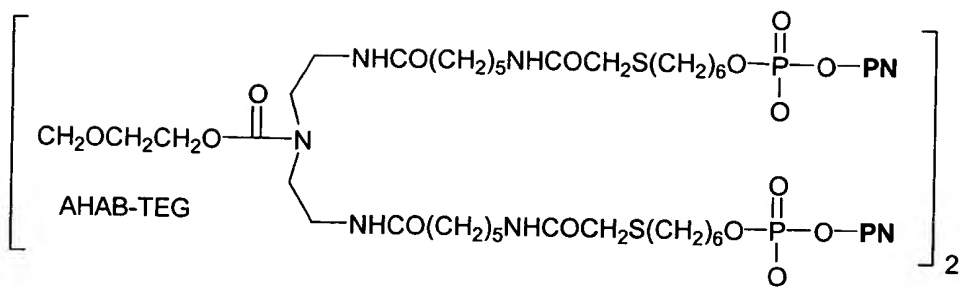
(b) administering to the individual the conjugate in an amount sufficient to increase the  $K_D'$ .

33. (Once Amended) A method of treating SLE in an individual, comprising: (a) assessing before or upon initiation of treatment an apparent equilibrium dissociation constant ( $K_D'$ ) for a dsDNA epitope in or of a conjugate and an antibody from the individual which specifically binds to double stranded DNA, said conjugate comprising (a) a non-immunogenic valency platform molecule and (b) two or more molecules comprising said epitopes, wherein the said epitopes are polynucleotides which specifically bind to an antibody from the individual which specifically binds to double stranded DNA and (b) administering to the individual the conjugate in an amount sufficient to increase the  $K_D'$ , wherein treatment is continued if  $K_D'$  is increased at least about 20% compared to  $K_D'$  before or upon initiation of treatment.

35. (Twice Amended) The method of claim [34] 33, wherein the polynucleotides consist essentially of the sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

36. (Twice Amended) The method of claim [34] 33, wherein the polynucleotides consist of the sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

39. (Once Amended) The method of claim [36] 35 wherein the platform molecule is



wherein PN is the polynucleotide.